Case: 4:24-cv-01549 Doc. #: 1 Filed: 11/19/24 Page: 1 of 41 PageID #: 1

IN THE UNITED STATES DISTRICT COURT FOR EASTERN DISTRICT OF MISSOURI

EXPRESS SCRIPTS, INC.,	
EVERNORTH HEALTH, INC.,	
ASCENT HEALTH SERVICES LLC	Case No
MEDCO HEALTH SERVICES, INC.	COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF
CAREMARK RX, L.L.C.;	
ZINC HEALTH SERVICES, LLC;	
OPTUMRX, INC.;	
OPTUMRX HOLDINGS, LLC;	
- and -	
EMISAR PHARMA SERVICES LLC,	
Plaintiffs,	
v.	
FEDERAL TRADE COMMISSION,	
LINA M. KHAN, in her official capacity as Commissioner and Chair of the United States Federal Trade Commission,	
REBECCA KELLY SLAUGHTER, in her official capacity as Commissioner of the United States Federal Trade Commission,	
ALVARO M. BEDOYA, in His official capacity as Commissioner of the United States Federal Trade Commission,	
D. MICHAEL CHAPPELL, in his official capacity as Federal Trade Commission Chief Administrative Law Judge,	

Defendants.

Plaintiffs Express Scripts, Inc. ("ESI"), Evernorth Health, Inc. ("Evernorth"), Ascent Health Services LLC ("Ascent"), and Medco Health Services, Inc. ("Medco") (together referred to as "Express Scripts"); Caremark Rx, L.L.C. and Zinc Health Services, LLC (together referred to as "Caremark"); and OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC (together referred to as "Optum") bring this Complaint for declaratory and injunctive relief against the Federal Trade Commission ("FTC" or "Commission"); Lina M. Khan in her official capacity as Commissioner and Chair of the FTC; Rebecca Kelly Slaughter and Alvaro M. Bedoya in their official capacities as Commissioners of the FTC; and the Honorable D. Michael Chappell, in his official capacity as Federal Trade Commission Chief Administrative Law Judge. Express Scripts, Caremark, and Optum allege as follows:

INTRODUCTION

1. Express Scripts, Caremark, and Optum bring this Complaint to enjoin the Federal Trade Commission's unconstitutional administrative proceeding against Plaintiffs. On September 20, 2024, three Commissioners (with two recused) initiated a complaint before the Commission's in-house administrative forum that would subvert bedrock constitutional principles of accountability and fairness in an attempt to transform significant aspects of an entire industry by regulatory fiat.

¹ "Express Scripts" is used herein for convenience to refer collectively to four of the entities named as respondents in the Commission's Complaint: ESI, Evernorth, Medco, and Ascent. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

² "Caremark" is used herein for convenience to refer collectively to two of the entities named as respondents in the Commission's Complaint: Caremark Rx, L.L.C. and Zinc Health Services, LLC. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

³ "Optum" is used herein for convenience to refer collectively to three of the entities named as respondents in the Commission's Complaint: OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC. It is not intended to be an admission or statement of the corporate form or relationship of these entities.

- 2. Plaintiffs Express Scripts, Caremark, and Optum are three competing pharmacy-benefit managers ("PBMs"). PBMs work with health plan sponsors, such as employers and unions, to manage prescription-drug benefits. PBMs negotiate with drug-manufacturers about the costs health plan sponsors will pay for drugs, and the amount those plans and employers will pay to fill prescriptions. In doing so, PBMs secure discounts and other savings for health plan sponsors—which in turn allows those health plan sponsors to reduce plan premiums and out-of-pocket costs for patients.
- 3. The Commission's administrative proceeding, however, seeks to restrict Plaintiff PBMs' ability to negotiate lower drug costs for their plan sponsor clients. The Commission's complaint accuses competing PBMs of nebulous unfair trade practices in negotiating drug costs, all based on a novel theory that Section 5 of the Federal Trade Commission Act—which prohibits "unfair methods of competition" and "unfair ... acts or practices"—gives the Commission roving license to define practices as unfair based on its own subjective policy preferences. The complaint proposes equally novel remedies: The Commission would upend present-day drug rebate contracts, forcing PBMs to revamp their entire contracting framework and countless contracts with drug manufacturers, health plan sponsors, and other private parties. Nor would the Commission stop there: The Commission reserves for itself the right to order "any other relief appropriate" without elaboration. FTC Compl., at 45, ¶ 4 (Notice of Contemplated Relief).
- 4. This sweeping attempt to reshape an entire industry via law enforcement would never pass muster in a U.S. District Court. It is therefore unsurprising that the Commission brought this action in its own captive tribunal, where the Commission decides the allegations and the claims, sets the rules, does the fact-finding, chooses what the law is, and determines the outcome. Indeed, in the past thirty years, the Commission has found a violation in *every* action brought

before it in its administrative proceeding, even as it notches many high-profile losses when it litigates in federal courts.

- 5. This type of stacked-deck administrative proceeding is fundamentally unfair. It also violates the U.S. Constitution in at least three ways.
- 6. First, the Commission's in-house proceeding violates Article III, which requires the type of claims at issue here—those involving private rights that traditionally would have been considered actions at law or equity—to be brought in federal court before an independent Article III judge. Here, the Commission is alleging classic common-law claims about purportedly unfair contracts and transactions among private market participants. And the Commission's requested relief would substantially and adversely affect private rights, including interfering with the PBMs' ability to contract with manufacturers and plan sponsors. The Constitution thus permits the FTC to bring these claims and seek this relief only in an Article III court.
- 7. Second, the FTC channeled its claims into its own in-house forum before Commissioners and an administrative law judge ("ALJ") that are unconstitutionally insulated from removal by the President and thus are insulated from democratic accountability. Specifically, the FTC Act restricts the President's authority to remove FTC Commissioners in violation of Article II of the Constitution, which reserves the power to execute the laws to the President alone. The FTC Commissioners clearly exercise executive power, and the Constitution prohibits statutory restrictions on the President's authority to remove FTC Commissioners. Relatedly, the ALJ presiding over the Commission's in-house proceeding is also unconstitutionally insulated from presidential accountability and supervision. The FTC's ALJs enjoy multiple layers of tenure protection, which the Supreme Court has already ruled unconstitutional in similar circumstances; indeed, one current FTC Commissioner—who is recused from participating in the administrative

proceeding—has stated explicitly his belief that the limitations on removal of the FTC's ALJs violate the Constitution.

- 8. Third, the Commission is depriving Plaintiffs of a fair and impartial tribunal in violation of the Due Process Clause of the Fifth Amendment. The same FTC Commissioners who voted to prosecute Plaintiffs for the conduct of others will now also serve as judge and jury empowered to find facts and reach conclusions of law. Giving the Commission the final word on the outcome of its own enforcement action violates due process. And these structural concerns are particularly pronounced here because the Commission's proceeding in this case is wholly partisan and biased, contrary to what Congress intended. Only the three Democratic Commissioners are participating in this matter, as the two Republican Commissioners have been recused for undisclosed reasons. And Chair Khan and the other non-recused Commissioners have already irrevocably made up their minds as to the allegations against Plaintiffs. A proceeding before the Commission with a foreordained outcome—like the one looming over Express Scripts, Caremark, and Optum—fails to provide the due process required and guaranteed by the Constitution.
- 9. The protections afforded by all of these constitutional rights—politically accountable agency officials and an independent, unbiased, Article III forum to adjudicate disputes—are particularly important here. The Commission's 45-page administrative complaint consists mostly of vague group pleading, underscoring that the Commission is unfairly bringing a single, consolidated action against competitors over their wholly *separate* alleged individual conduct. And the substance of that administrative complaint raises novel theories that historically have drawn skepticism from federal courts. The Commission alleges a "broken system" in which drug manufacturers "preserve the manufacturers' own profits" by increasing their list prices. According to the Commission, this harms certain patients who, as a result of plan design decisions

by plan sponsors, have out-of-pocket costs (copayments) tied to list prices. The Commission's Complaint seeks to fix this purported "broken system" by holding Express Scripts, Caremark, and Optum, which allegedly "administer approximately 80% of all prescriptions in the United States," liable for drug prices they do not set. The Commission also seeks to interfere with Plaintiffs' ability to offer programs and tools to plan sponsors to lower drug costs, even though plan sponsors ultimately decide whether to adopt them. In targeting purported "middlemen," the Commission is attacking the one critical element of the drug distribution and benefit process that *lowers* net drug costs for employers, labor unions, and the government itself. This turns the antitrust and consumer protection laws—which promote, not punish, conduct that spurs competition among manufacturers and lowers prices—on their heads. And if left unchecked, the action will have wide-ranging implications for the American economy.

10. But this Court ultimately need not decide the merits of these contentions. Instead, it need only conclude that the Commission's claims cannot proceed in administrative proceedings that violate multiple constitutional safeguards. Moreover, forcing Plaintiffs to defend themselves in an unconstitutional, illegal, and misguided proceeding would cause irreparable injury that could not be remedied on appeal. The Commission's administrative proceeding must be enjoined.

PARTIES

- 11. Plaintiff Express Scripts, Inc. is a Delaware corporation with its principal office or place of business at 1 Express Way, Saint Louis, MO 63121.
- 12. Plaintiff Evernorth Health, Inc. is a Delaware corporation with its principal office or place of business at 1 Express Way, Saint Louis, MO 63121.
- 13. Plaintiff Medco Health Services, Inc. is a Delaware corporation with its principal office or place of business at 1 Express Way, Saint Louis, MO 63121.

- 14. Plaintiff Ascent Health Services LLC is a Delaware limited liability company with its principal place of business at Muhlentalstrasse 36, 8200 Schaffhausen, Switzerland.
- 15. Plaintiff Caremark Rx, L.L.C. is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, RI. Caremark Rx, L.L.C. is a wholly owned indirect subsidiary of CVS Health Corporation.
- 16. Plaintiff Zinc Health Services, LLC is a Delaware limited liability company with its principal place of business at 8300 Norman Center Drive, Suite 850, Bloomington, MN. Zinc Health Services, LLC is a majority owned indirect subsidiary of CVS Health Corporation.
- 17. Plaintiff OptumRx, Inc. is a California corporation, with its principal place of business at 1 Optum Circle, Eden Prairie, MN. OptumRx, Inc. is a wholly owned indirect subsidiary of UnitedHealth Group Inc.
- 18. Plaintiff OptumRx Holdings, LLC is a California corporation, with its principal place of business at 1 Optum Circle, Eden Prairie, MN. OptumRx Holdings, LLC is a wholly owned indirect subsidiary of UnitedHealth Group Inc. and the direct parent company of OptumRx, Inc.
- 19. Plaintiff Emisar Pharma Services LLC is a Delaware limited liability company. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc.
- 20. Defendant Federal Trade Commission is an agency of the United States government whose principal place of business is at 600 Pennsylvania Avenue, NW, Washington, DC 20580.
- 21. Defendant Lina M. Khan is a Commissioner and the Chair of the FTC. Plaintiffs sue Chair Khan in her official capacity.
- 22. Defendant Rebecca Kelly Slaughter is a Commissioner of the FTC. Plaintiffs sue Commissioner Slaughter in her official capacity.

23. Defendant Alvaro M. Bedoya is a Commissioner of the FTC. Plaintiffs sue Commissioner Bedoya in his official capacity.

24. Defendant the Honorable D. Michael Chappell is the FTC Chief ALJ. Plaintiffs sue Chief ALJ Chappell in his official capacity.

JURISDICTION AND VENUE

- 25. This Action arises under the Constitution and laws of the United States, and this Court has federal question jurisdiction over this Action pursuant to the U.S. Constitution and 28 U.S.C. § 1331. See Axon Enter., Inc. v. FTC, 598 U.S. 175 (2023).
- 26. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (e), including because at least one plaintiff has its principal place of business in this district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district.
- 27. This Court is authorized to grant the relief prayed for under the U.S. Constitution; the All Writs Act, 28 U.S.C. § 1651(a); and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a)-2202.

BACKGROUND

The Federal Trade Commission's Unconstitutional Structure and Process A.

28. The Federal Trade Commission is composed of five Commissioners who are appointed by the President by and with the advice and consent of the United States Senate. The President can remove an FTC Commissioner only "for inefficiency, neglect of duty, or malfeasance in office." The FTC's ALJs, in turn, are removable only for "good cause" as determined by the Merit Systems Protection Board, a separate federal agency that adjudicates

⁴ 15 U.S.C. § 41. ⁵ 5 U.S.C. § 7521(a), (b)(1).

personnel matters. Members of the Merit Systems Protection Board cannot be removed by the President except for "inefficiency, neglect of duty, or malfeasance in office." Even "dual layer[s] of protection" from removal have been held to be unconstitutional with respect to SEC ALJs and other agency officials. And the Commission's ALJs are further removed from democratic accountability.

- 29. The Commission is intended to be bipartisan. By statute, no more than three of the Commissioners can be members of the same political party.⁸ The Commission currently has three Democratic members (Chair Khan, Commissioner Slaughter, and Commissioner Bedoya) and two Republican members (Commission Holyoak and Commissioner Ferguson).
- 30. The Commission has statutory authority to exercise a host of executive functions. In particular, the Commission has broad investigative powers to support its "law enforcement" efforts. The Commission can bring administrative proceedings against a person or corporation subject to its jurisdiction for allegedly engaging in unfair methods of competition or unfair or deceptive acts or practices. The Commission also enforces myriad other laws and trade regulations. The Commission itself touts that "in total the Commission has enforcement or administrative responsibilities under more than 70 laws." In the 1970s, Congress amended the FTC Act by giving the Commission substantial additional enforcement authority—authority that

⁶ 5 U.S.C.§ 1202(d).

⁷ *Jarkesy v. SEC*, 34 F.4th 446, 463-465 (5th Cir. 2022); *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, at 514 (2010).

⁸ 15 U.S.C. § 41.

⁹ FTC, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority (revised May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority.

¹⁰ 15 U.S.C. § 45.

¹¹ FTC, Enforcement (last visited Nov. 17, 2024), https://www.ftc.gov/enforcement.

the Supreme Court has recently characterized as "quintessentially executive power." ¹² The Commission has discretion to bring actions in an in-house administrative process or in a federal district court. ¹³

31. Administrative enforcement actions are initiated by a vote of the Commission to issue a complaint. The actions are heard in the first instance by an ALJ.¹⁴ The FTC Commissioners do not observe witnesses or scrutinize other evidence but only review the written record post-hearing. Nevertheless, when deciding whether to adopt or modify an ALJ's recommended decision, the Commission owes no deference whatsoever to an ALJ's factual findings.¹⁵

B. The Commission's Insulin Investigation and Administrative Action

- 32. In 2022, the Commission launched an investigation into insulin pricing. In June 2022 the Commission issued Civil Investigative Demands to Express Scripts, Caremark, and Optum seeking documents and data. Although the Commission now seeks relief that sweeps more broadly and implicates *all* drugs, the Commission's investigation was focused on insulin costs.
- 33. On September 20, 2024, the Commission voted to issue an administrative complaint naming as respondents Express Scripts, Caremark, and Optum. Only the Commission's three Democratic Commissioners voted to issue the administrative complaint; the two Republican Commissioners are recused from the Commission's proceedings for reasons not disclosed to the public or to Express Scripts, Caremark, and Optum.
- 34. The Complaint alleges that Express Scripts, Caremark, and Optum work with clients, often referred to as "plan sponsors," which include employers (including federal

¹² Seila Law LLC v. Consumer Fin. Prot. Bureau, 591 U.S. 197, 219 (2020).

¹³ 15 U.S.C. §§ 45, 53(b)(2), 57b.

¹⁴ 16 C.F.R. § 3.41.

¹⁵ Revisions to Rules of Practice, 88 Fed. Reg. 42,872 (July 5, 2023), *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/p072104-amendments-to-part-3-rules-frn.pdf.

government agencies offering prescription drug benefits to their employees), health insurance plans, labor unions, government programs, and other groups that offer prescription drug benefits.¹⁶ According to the Complaint, Express Scripts, Caremark, and Optum collectively "administer approximately 80% of all prescriptions in the United States," and effectively represent the lion's share of the industry.¹⁷

- 35. As the Commission repeatedly admits, Express Scripts, Caremark, and Optum do not set the prices of prescription drugs. Rather, drug manufacturers set the list price for prescription drugs, called the wholesale acquisition cost ("WAC"), and also set net list prices (list prices net of any rebates or discounts) based on what they agree to offer to different groups. ¹⁸
- 36. The Complaint recognizes that Express Scripts, Caremark, and Optum each "[n]egotiate with pharmaceutical manufacturers for rebates [from manufacturers' list prices] on behalf of their clients." PBMs like Express Scripts, Caremark, and Optum and their clients use drug formulary design to drive competition between manufacturers of clinically equivalent drugs, such as insulin drugs, in order to "extract price concessions from drug manufacturers." (A drug formulary is a list of prescription drugs covered by a health plan, which often uses separate tiers to "prefer" drugs that are lower cost to the plan sponsor and its members. One way that PBMs secure cost savings for health plan sponsors is by seeking conditional rebates (i.e., discounts) from

¹⁶ *Id*.

¹⁷ Complaint ¶ 3, *In re Caremark Rx, L.L.C., et al.*, Docket No. 9437 (F.T.C. Sept. 20, 2024) (hereinafter "Complaint") https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx zinc health services et al part 3 complaint corrected public.pdf.

 $[\]overline{\ }^{18}$ Id. $\P\P$ 2, 6, 9, 40, 119, 135, 236-241.

¹⁹ *Id.* ¶ 28.

 $^{^{20}}$ *Id.* ¶ 38.

²¹ *Id.* ¶ 32.

a drug's list price that the manufacturer must pay after a health plan sponsor prefers the manufacturer's drug on the plan sponsor's formulary.

- Optum, determine which formularies to adopt and how manufacturer rebates are distributed. Express Scripts, Caremark, and Optum offer standard formularies that include preferences for low net-cost drugs (which account for rebates off of list price) as well as open formularies that do not include preferences. Plan sponsors decide what type of formulary fits with their plan design, or design their own. Plan sponsors may choose to allocate some or all of the rebates they receive to members at the point-of-sale as a way to reduce out-of-pocket costs for members who buy rebated drugs. As another option, a plan sponsor may require Express Scripts, Caremark, and Optum to transfer all of the rebates to the plan sponsor to be used as it sees fit—for example, to reduce premiums, reduce out-of-pocket member costs, and/or improve benefits. The Complaint admits that plan sponsors typically design their prescription benefit plans so that members pay less for drugs that are included or preferred on the plan sponsor's formulary compared to drugs not included or not preferred on the formulary.
- 38. As the Complaint further admits, through competition among manufacturers of clinically equivalent drugs for formulary placement, PBMs Express Scripts, Caremark, and Optum negotiate substantial rebates off the list price of insulin drugs during the relevant time period.²⁷

²² *Id.* ¶¶ 4, 50, 55, 60, 66, 184, 196-197.

²³ *Id*. ¶ 50.

²⁴ *Id.* ¶¶ 55, 66, 184, 196-197.

²⁵ *Id*.

 $^{^{26}}$ *Id.* ¶ 4.

²⁷ See, e.g., id. ¶¶ 44, 117.

These discounts, in turn, reduce insulin costs for plan sponsors, the PBMs' clients.²⁸ PBMs compete with one another to provide the greatest savings to plan sponsors.²⁹

39. Remarkably, the Complaint alleges that competition among Express Scripts, Caremark, and Optum to offer the largest drug cost savings to their plan sponsor clients is an "unfair method of competition" and an "unfair practice" that violates Section 5 of the Federal Trade Commission Act. That is so, the Complaint alleges, because plan sponsors often choose "closed" formularies, where manufacturers have to compete on price for a position on the formulary, over "open" formularies, which offer multiple manufacturers the opportunity to be listed. Express Scripts, Caremark, and Optum offer both types of formularies to their clients. The Complaint alleges that insulin manufacturers then raise their list prices in order to "compensate" themselves "for the very high rebates" and to "preserve the manufacturers' own profits. Thially, according to the Complaint, certain diabetic patients may pay the higher list price for insulin drugs at the pharmacy either because they are uninsured (in which case Express Scripts, Caremark, and Optum are not providing services relating to their prescription at all) or because the plan sponsor has decided to structure the drug benefit to include cost sharing based on list prices (also not a decision made by Express Scripts, Caremark, or Optum).

40. In addition to alleging that generating competition between drug manufacturers is somehow "unfair," the Complaint's allegations also overwhelmingly lump together the "big three" respondent PBMs (Plaintiffs in this case), and often the entire PBM industry. In paragraph after paragraph—nearly 140 times in the Complaint—the Commission refers to the "PBM

²⁸ *Id.* ¶ 55.

 $^{^{29}}$ Id. ¶ 106.

³⁰ *Id.* ¶¶ 34-37, 174

³¹ Id ¶¶ 6 123

³² *Id.* ¶¶ 60-61, 66-67.

Respondents," assuming that they act in lockstep, attributing the conduct of other PBMs to the individual PBMs. In many other places, the Complaint refers to the practices of PBMs generically, suggesting that the Commission is attacking the same practices employed by the whole industry. Indeed, allegations about Express Scripts' individual conduct are only addressed in 24 paragraphs throughout the 274-paragraph Complaint.³³ Allegations about Caremark's individual conduct are only addressed in 31 paragraphs throughout the Complaint.³⁴ Allegations about Optum's individual conduct are only addressed in 28 paragraphs throughout the Complaint.³⁵

- 41. Although it names multiple PBMs as respondents, the Complaint contains no allegations that respondents engaged in any collusive conduct in violation of the antitrust laws. Nor does it accuse Express Scripts, Caremark, or Optum of engaging in any common scheme or other coordinated effort with the other respondent PBMs. In its scant individualized allegations, the Complaint is clear that Express Scripts, Caremark, and Optum act individually and in competition with one another—not in coordination. For example:
 - The PBMs did not introduce "exclusive" formularies at the same time. Caremark allegedly first introduced one in 2012, Express Scripts in 2014, and Optum in 2016.³⁶
 - Those formularies vary widely in how narrow or "exclusive" they are across plan sponsors and PBMs.³⁷
 - Express Scripts, Caremark, and Optum negotiated different rebates with the same insulin manufacturers. 38

 $^{^{33}}$ See id. ¶¶ 102, 104, 110, 111, 114, 117, 145, 149, 154, 157, 168, 170, 171, 174, 178, 181, 188, 199, 200, 211, 228, 232, 246, 250.

³⁴ See id. ¶¶ 103, 110, 111, 114, 116, 137, 146, 150, 165, 168, 172, 173, 176, 178, 179, 184, 185, 186, 187, 188, 189, 192, 196, 198, 200, 208, 211, 212, 217, 228, 245.

³⁵ See id. ¶¶ 44, 46, 54, 105, 108, 111, 118, 124, 145, 147, 155, 169, 173, 174, 180, 182, 190, 191, 196, 200, 209, 223, 228, 229, 232, 247, 250.

 $^{^{36}}$ Id. ¶¶ 103-105.

 $^{^{37}}$ Id. ¶ 114.

 $^{^{38}}$ *Id.* ¶ 44.

- Express Scripts, Caremark, and Optum entered into rebate arrangements with different manufacturers, preferring different drugs than each other. For example, "in 2023, Optum preferred Sanofi's long-acting insulins (Lantus and Toujeo) and excluded both Novo's long-acting insulins (Levemir and Tresiba) and Lilly's long-acting insulin (Basaglar) from its flagship Premium Formulary. In the same year, though, Caremark and ESI both preferred Novo's Levemir and Tresiba and excluded Sanofi's Lantus from their flagship formularies."³⁹
- Express Scripts, Caremark, and Optum independently negotiate with drug manufacturers to determine appropriate administrative, data, and WAC-based fees. 40 The fees vary for different drug manufacturers.
- 42. Although the facts alleged in the Complaint relate overwhelmingly to insulin prices and formulary placements, the relief the Commission seeks is strikingly broad and would extend to *all* drugs. Specifically, the Complaint seeks to "prohibit Respondents from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary," and to "prohibit Respondents from accepting compensation based on a drug's list price or a related benchmark."⁴¹
- 43. The Commission also expressly seeks to regulate Plaintiffs' clients, *i.e.*, the sponsors of prescription drug benefits. The Commission would "prohibit [Plaintiffs] from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates." Such relief, if applied to plan sponsors' plan designs choices, would completely reshape how plan sponsors design prescription drug coverage in the United States.
- 44. Express Scripts, Caremark, and Optum accepted service of the Commission's Complaint on September 25, 2024. The respondents' answers to the Commission's voluminous

 $^{^{39}}$ *Id.* ¶ 111.

⁴⁰ *Id.* ¶¶ 46, 48-49.

⁴¹ *Id.* at 44, ¶¶ 1-2 (Notice of Contemplated Relief).

⁴² *Id.* at 44-45, ¶ 3 (Notice of Contemplated Relief).

Complaint were due just 14 days later, on October 9. The Commission has ordered the hearing on its Complaint to commence before an ALJ 11 months later starting on August 27, 2025.

ALLEGATIONS

- A. Article III Prohibits the FTC From Adjudicating Private Rights and Restructuring Private Parties' Contracts.
- 45. The Commission is constitutionally barred from adjudicating in-house the claims or granting the remedies it seeks in this administrative proceeding.
- 46. Under Article III of the Constitution, the "judicial Power ... extend[s] to all Cases, in Law and Equity, arising under th[e] Constitution, the Laws of the United States, [and] to Controversies to which the United States shall be a Party."⁴³ Under "the basic concept of separation of powers," the "judicial Power ... can no more be shared with another branch" than legislative or executive powers can be shared with other branches. ⁴⁴ Applying this principle, the Supreme Court has explained that cases involving a "private right" must be adjudicated by Article III courts. ⁴⁵ Thus, Article III prohibits Congress from "withdraw[ing] from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty" and assigning it to administrative agencies. ⁴⁶ Suits involving "private rights," i.e., "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789," are the quintessential suits that Congress "may not ... remove[] from Article III courts."
- 47. Allowing the Commission to adjudicate its complaint via in-house administrative proceedings vitiates the Article III guarantee to a federal judicial forum for multiple reasons.

⁴³ U.S. Const. art. III, § 2.

⁴⁴ Stern v. Marshall, 564 U.S. 462, 483 (2011).

⁴⁵ Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 56 (1989).

⁴⁶ SEC v. Jarkesy, 144 S. Ct. 2117, 2134 (2024) (citing Murray's Lessee v. Hoboken Land & Improvement Co., 59 U.S. 272, 284 (1855)).

⁴⁷ Jarkesy, 144 S. Ct. at 2132 (internal quotations omitted).

48. As an initial matter, the Commission's claims are in the nature of an action at common law. The Commission accuses PBMs of committing "unfair method[s] of competition" and "unfair act or practice[s]" in contracting with other private parties, in violation of § 5 of the FTC Act. Common law actions have long existed for unlawful restraints of trade and unfair or unconscionable business practices, predating federal statutory antitrust and consumer protection laws. For example, the common law recognized a remedy for lack of fairness and honesty in the sale of goods between private parties. Unfair competition was a "common law" remedy originally "relat[ing] to "palming off of one's goods as those of a rival trader," but "expanded" to include "acts which lie outside the ordinary course of business and are tainted by fraud or coercion or conduct otherwise prohibited by law." The FTC itself looks to the common law as the first factor to determine if a practice is "unfair."

49. While federal law has expanded the scope of unfair competition, that action retains its common-law origins. Congress intended that the FTC and courts to draw from the "idea of unfair trade at common law" and apply the "same principles and tests that have been applied under the common law" to new situations.⁵² Because the cause of action FTC invokes "close[ly]

⁴⁸ E.g., Complaint ¶¶ 261, 267, 274.

⁴⁹ *E.g.*, 3 William Blackstone, Commentaries *164 ("If any one cheats me with fal[s]e cars or dice, or by "fal[s]e weights and mea[s]ures, or by [s]elling one commodity for another, an action on the ca[s]e al[s]o lies again[s]t him for damages, upon the contract which the law always implies, that every tran[s]action is fair and hone[s]t.").

⁵⁰ See A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 531-532 (1935) (citations omitted).

⁵¹ See FTC, Statement of Basis and Purpose of Trade Regulation Rule 408, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8325, 8355 (July 2, 1964) (noting as first factor for discerning "unfair acts or practices" includes whether the practice was considered "unfair" under the common law).

⁵² See Sears, Roebuck & Co. v. FTC, 258 F. 307, 310-11 (7th Cir. 1919).

relate[s]" to a historical common-law action, only federal courts—not agencies—can adjudicate the action.⁵³

- 50. The Commission's claims also implicate the PBM Plaintiffs' contract rights, which are the paradigmatic private rights that must be adjudicated in Article III courts. ⁵⁴ The FTC seeks to impose sweeping cease and desist orders that would abrogate, and force the PBM Plaintiffs to restructure, hundreds, if not thousands, of contracts with private market participants and prohibit similar contracts in the future, change how Plaintiffs negotiate discounts off list prices with drug manufacturers, and limit benefit design options for plan sponsors and their members. ⁵⁵ By seeking relief in this proceeding that will overturn the PBM Plaintiffs' settled economic expectations, as well those of numerous private third parties, the FTC's Complaint clearly concerns Plaintiffs' property rights in their contractual agreements and, therefore, concerns Plaintiffs' private rights. ⁵⁶ Going forward, Plaintiffs' freedom to contract with manufacturers and plan sponsors in these areas would be permanently and substantially restricted if the Commission were to obtain the expansive cease-and-desist order it requests in its Complaint.
- 51. This putative remedy is also fundamentally equitable, which Article III requires federal courts, not agencies, to impose.⁵⁷ Here, the FTC seeks a broad cease-and-desist order rescinding private parties' contracts that the FTC deems unlawful and prohibiting those same private parties from entering into similar contracts in the future.⁵⁸ Cease-and-desist orders are

⁵³ See Jarkesy, 144 S. Ct. at 2129, 2131.

⁵⁴ Career Colls. & Schs. of Tex. v. Dep't of Educ., 98 F.4th 220, 248 (5th Cir. 2024).

⁵⁵ Compl Notice of Contemplated Relief, ¶¶ 1-3; Compl. ¶¶ 234-254.

⁵⁶ Axon, 598 U.S. at 197 (Thomas, J., concurring) ("Disposition of private rights to life, liberty, and property" was understood to 'fal[l] within the core of the judicial power, whereas disposition of public rights [was] not."").

⁵⁷ Jarkesy, 144 S. Ct. at 2134 (citation omitted).

⁵⁸ See Complaint, $\P\P$ 234-254; *id.* at 44-45, $\P\P$ 1-3 (Notice of Contemplated Relief).

nothing more than injunctions by another name, and injunctions are inherently equitable remedies. Likewise, remedies rescinding current contracts and enjoining the entering into of similar contracts on a going-forward basis have been adjudicated by courts of equity for centuries. Because Article III courts cannot adjudicate traditional equitable remedies for claims involving private rights, the Commission's in-house proceeding is unlawful.

52. The FTC cannot invoke the so-called public rights exception to operate free from Article III strictures. The "public rights" exception is "narrow" and encompasses only a limited "class of cases concerning ... matters [that] historically could have been determined exclusively by the executive and legislative branches, even when they were presented in such form that the judicial power was capable of acting on them." Here, courts and juries traditionally resolved analogous unfair-competition claims. For example, common law actions have long existed for unlawful restraints of trade and unfair or unconscionable business practices, predating federal antitrust and consumer protection law.

B. FTC Commissioners Are Unconstitutionally Insulated from Presidential Removal.

53. Article II of the Constitution vests "the executive Power" entirely in the President,⁶¹ who must "take Care that the Laws be faithfully executed."⁶² By vesting all of the Nation's executive power in a single, elected official, the Constitution ensures that the people have the ultimate say in how the laws are executed. Yet the FTC's Commissioners are immune from presidential oversight, even "as they exercise[] power in the people's name."⁶³

⁵⁹ *Jarkesy*, 144 S. Ct. at 2127, 2132 (cleaned up).

 $^{^{60}}$ Supra, ¶¶ 48-49.

⁶¹ U.S. Const. art. II, § 1, cl. 1.

⁶² Id 8 3

⁶³ Free Enter. Fund, 561 U.S. at 497.

54. The Commission has broad authority to "investigate" people and corporations engaging in "commerce" for allegedly committing "unfair or deceptive acts or practices" or engaging in "[u]nfair methods of competition." FTC Commissioners "set enforcement priorities" and "initiate prosecutions" against people and corporations for alleged violations, and once administrative proceedings are instituted, FTC Commissioners "oversee [those] adjudications." FTC Commissioners also can issue final decisions in the administrative adjudications, order people and corporations to cease and desist from engaging in business activities the Commissioners believe to be unlawful, and "seek daunting monetary penalties against private parties on behalf of the United States in federal court."

55. Yet under the Federal Trade Commission Act, Commissioners of the FTC may only be removed by the President for "inefficiency, neglect of duty, or malfeasance in office." The FTC Commissioners thereby enjoy a layer of statutory protection from removal, allowing them to act with less concern that they may be removed by the President. This constitutional problem is particularly troubling at the present moment because Chair Khan's term expired on September 25, 2024, but the newly-elected President, who did not appoint her, will be unable to remove her from the Commission upon taking office. Nor will the newly elected President be able to remove the other two Democratic Commissioners—the only other Commissioners who voted to issue the Complaint against Plaintiffs, if he wished to.

56. The Commission's law enforcement actions, including those directed against Express Scripts, Caremark, and Optum, are a substantial exercise of executive authority. FTC

⁶⁴ 15 U.S.C. §§ 45(a)(1), 46(a); see Collins v. Yellen, 594 U.S. 220, 230 (2021).

⁶⁵ See Seila Law, 591 U.S. at 200, 225; 15 U.S.C. §§ 45(m), 53; 16 C.F.R. §§ 3.11, 3.23, 3.52-.54.

⁶⁶ See Seila Law, 591 U.S. at 218-219; 15 U.S.C. § 45(b), 45(m); 16 C.F.R. § 3.54.

⁶⁷ 15 U.S.C. § 41.

Commissioners must therefore be subject to unqualified removal by the President. Because the FTC Commissioners are insulated from presidential removal by a statutory for-cause removal provision, the Commission's structure contravenes constitutional principles, and its law enforcement actions are invalid.

- 57. That the FTC has five Commissioners, not one, does not immunize it from constitutional scrutiny or presidential accountability. The Supreme Court endorsed for-cause removal protection for the FTC's Commissioners in *Humphrey's Executor v. United States*, 295 U.S. 602 (1935). But that limited exception to the rule that agency heads must be fully accountable to the President turned upon the Commission "as it existed in 1935." At that juncture, the Supreme Court viewed the circa-1935 FTC "as exercising 'no part of the executive power'" and functioning as "an administrative body' that performed 'specified duties as a legislative or judicial aid." In the Court's view at the time, the Commission in 1935 made only "investigations and reports' to Congress" and "recommendations to courts as a master in chancery."
- 58. The Commission exercises significantly more executive power today. And the Supreme Court has emphasized that even speaking of the Commission's powers in 1935, the "Court's conclusion that the FTC did not exercise executive power has not withstood the test of time." [I]t is hard to dispute that the powers of the FTC at the time of *Humphrey's Executor* would at the present time be considered executive, at least to some degree." Under modern

⁶⁸ Seila Law, 591 U.S. at 215 (quoting Humphrey's Executor, 295 U.S. at 628).

 $^{^{69}}$ *Id*.

⁷⁰ *Id.* at 216 n.2.

 $^{^{71}}$ Morrison v. Olson, 487 U.S. 654, 689 n.28 (1988); accord Seila Law, 591 U.S. at 216 n.2.

precedent, the FTC's modern powers require that its Commissioners must be fully accountable to presidential supervision and removable at will. ⁷²

C. FTC ALJs are Executive Officers Who Are Unconstitutionally Insulated from Presidential Removal.

- 59. FTC ALJs are "inferior" officers within the Executive Branch. They serve indefinitely and exercise significant discretion and administrative authority in conducting adversarial hearings in the Commission's in-house proceedings. The Commission "delegates the initial performance of statutory fact-finding functions and initial rulings on conclusions of law" to ALJs. The ALJs conduct hearings, control discovery, issue subpoenas, make decisions on the admissibility of evidence, and issue orders to keep proceedings moving. At the end of administrative proceedings, the ALJs must file "a recommend decision" that is "based on a consideration of the whole record relevant to the issues decided" and "include[s] a statement of recommended findings of fact ... and recommended conclusions of law," as well as a "proposed rule or order." Accordingly, ALJs "determine, on a case-by-case basis, the policy of an executive branch agency," "fill[ing] statutory and regulatory interstices comprehensively with [their] own policy judgments." The FTC then reviews ALJ decisions and may "adopt, modify or set aside the recommended findings, recommended conclusions, and proposed rule or order."
- 60. Despite the significant executive power FTC's ALJs exercise in administrative proceedings, the FTC can only remove the ALJs "for good cause established and determined by

⁷² To the extent the Court concludes that *Humphrey's Executor* is controlling, Express Scripts, Caremark, and Optum reserve all rights to argue the Supreme Court should overrule *Humphrey's Executor*.

⁷³ 16 C.F.R. § 0.14.

⁷⁴ *Id.* §§ 3.42(c), 3.43.

⁷⁵ *Id.* § 3.51(a), (c)(1).

⁷⁶ Sec'y of Educ. Review of ALJ Decisions, 15 Op. O.L.C. 8, 14-15 (1991).

⁷⁷ 16 C.F.R. §§ 3.53, 3.54(a).

the Merits Systems Protection Board," and only "on the record after opportunity for [a] hearing" before that Board.⁷⁸ And the FTC Commissioners who can initiate removal proceedings for the ALJs are themselves removable by the President only for-cause.⁷⁹

- 61. As a result, FTC ALJs serve under multiple layers of for-cause removal protection from Presidential supervision, conflicting with the requirement that, under Article II, the President must have "the ability to remove executive officials" —including FTC ALJs—at will, given that "[t]he entire 'executive Power' belongs to the President alone."
 - D. The Commission's Adjudicative Process Violates Plaintiffs' Due Process Rights.
 - 1. The Administrative Process Unconstitutionally Permits the FTC to Play the Role of Prosecutor, Judge, and Jury in a Fundamentally Unfair Proceeding
- 62. "[A] fair trial in a fair tribunal is a basic requirement of due process." ⁸² "[W]hen the same person serves as both accuser and adjudicator in a case," an "unconstitutional potential for bias exists." ⁸³ Yet here, rather than go to federal court, the FTC chose to pursue its claims against Plaintiffs through its in-house adjudicatory system that "combine[s] the functions of investigator, prosecutor, and judge under one roof." ⁸⁴
- 63. The FTC Commissioners decide the cases in which cases the Commission brings a complaint, which factual allegations to make against each respondent, and which legal claims to assert.⁸⁵ Then, Commission staff adjudicate the case in front of an FTC ALJ in a proceeding

⁷⁸ 5 U.S.C. § 7521(a), (b)(1).

⁷⁹ 15 U.S.C. § 41.

⁸⁰ Seila Law, 591 U.S. at 213.

⁸¹ *Id.* (quoting Art. II, § 1).

⁸² Caperton v. A.T. Massey Coal Co., 566 U.S. 868, 876 (2009) (internal quotations omitted).

⁸³ Williams v. Pennsylvania, 579 U.S. 1, 8 (2016).

⁸⁴ *Axon*, 598 U.S. at 215 (Gorsuch, J., concurring).

^{85 16} C.F.R. § 3.11(a).

governed by "relaxed rules of procedure and evidence—rules [the FTC] make[s] for [itself]."⁸⁶ The Federal Rules of Civil Procedure and Federal Rules of Evidence that apply in federal courts do not apply in FTC proceedings. Then, even if the FTC loses before the ALJ despite all the procedural advantages, the FTC Commissioners review the ALJ's decision *de novo*—including the ALJ's factual findings and credibility determinations.⁸⁷ Thus, the ultimate decision whether to find liability is up to the very Commissioners who voted to issue a complaint bring the case in the first place.

- 64. Compounding the unfairness to Plaintiffs, the proceeding's timeline is highly compressed. In this case, while the Commission has spent more than two years conducting an investigation, Plaintiffs have to be trial-ready in a matter of months.
- 65. Since Chair Khan began her tenure at the Commission, the Commission has further stacked the deck to weaken due process for respondents and give the Commission even more pronounced procedural advantages in in-house proceedings. Under Chair Khan, the Commission voted in June 2023 to alter the Commission's rules of practice by converting an ALJ's ruling from an "initial decision"—which would automatically become the Commission's decision absent challenge—to a purely "recommended decision" that the Commission must vote to adopt.
- 66. Unsurprisingly, the "odds [are] stacked against" anyone against whom the FTC brings administrative proceedings.⁸⁸ For example, as the Ninth Circuit stated in its 2021 opinion in the *Axon* case, "Axon claims—and FTC does not appear to dispute—that FTC has not lost a single case in the past quarter-century. Even the 1972 Miami Dolphins would envy that type of

⁸⁶ Axon, 598 U.S. at 215 (Gorsuch, J., concurring); see 16 C.F.R. §§ 3.1, 3.43, 3.51.

⁸⁷ 16 C.F.R. § 3.54.

⁸⁸ See Jarkesy, 144 S. Ct. at 2141 (Gorsuch, J., concurring).

record."⁸⁹ Attached to this Complaint is a chart identifying all FTC administrative proceedings under Part 3 of the FTC's rules updated by the Commission between January 1, 2015, and November 18, 2024, in which there was a ruling on liability by an ALJ and/or the Commission. *See* Ex. 1. The chart was compiled from the FTC's website listing adjudicative proceedings. As the chart illustrates, the Commission prevailed in each relevant instance. *See id.* The FTC's winloss record during in-house proceedings raises serious due process concerns, especially when combined with the procedural advantages the FTC has granted to itself.

- 67. Compounding the problem, the FTC's statutory scheme deprives courts of *de novo* review at the back end. Federal courts must treat FTC factual findings as "conclusive" "if supported by evidence," a highly deferential standard of review. 90 "The reviewing court also cannot take its own evidence—it can only remand the case to the agency for further proceedings." Thus, even on appellate review, courts are required to "put a thumb (or perhaps two forearms) on the agency's side of the scale." That is the very opposite of the separation of powers that the Constitution demands."
- 68. Given that the FTC Commissioners owe no deference to an ALJ decision, and the FTC contends that federal court of appeals *must* affirm the Commission's factual findings if they meet the deferential "substantial evidence" standard (a more lenient standard than the one applied

⁸⁹ See Axon Enter., Inc. v. FTC, 986 F.3d 1173, 1187 (9th Cir. 2021), rev'd and remanded, 598 U.S. 175 (2023); see also David Balto, Can the FTC be a Fair Umpire?, THE HILL (Aug. 14, 2013), https://thehill.com/blogs/congress-blog/economy-a-budget/159122-can-the-ftc-be-a-fair-umpire; A. Douglas Melamed, Comments to FTC Workshop Concerning Section 5 of the FTC Act (Oct. 14, 2008), https://www.ftc.gov/sites/default/files/documents/public_comments/section-5-workshop-537633-00004/537633-00004.pdf.

⁹⁰ 15 U.S.C. § 45(c).

⁹¹ Axon, 598 U.S. at 197 (Thomas, J., concurring) (citing 15 U.S.C. § 45(c)).

⁹² *Id.* at 203 (citation omitted).

⁹³ *Jarkesy*, 144 S. Ct. at 2139.

to a district court's findings of fact), Plaintiffs will forever be denied a fair opportunity to have the factual record considered by a neutral factfinder and decisionmaker. These profound deficiencies in process deny Plaintiffs their constitutional rights to due process because "a 'fair trial in a fair tribunal is a basic requirement of due process."

69. Ultimately, the Commission may be entitled to serve as prosecutor *or* as judge. But the Constitution forbids the Commission from doing both in the same matter. "Due process guarantees 'an absence of actual bias' on the part of a judge," and "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case." Here, the Commission endeavors to inhabit both roles simultaneously in clear violation of the Constitution. As a result, "the odds [are] stacked against" Plaintiffs in a manner that violates their due process rights. 96

2. The Commission Has Prejudged the Facts and Law as to the PBM Plaintiffs, Rendering this Enforcement Action Fundamentally Unfair

70. The structural unfairness of the Commission's proceedings is especially problematic here, because the Commission has demonstrated that it has already prejudged the case against Express Scripts, Caremark, and Optum, and there is no opportunity for a fair proceeding. The current FTC is led by a Chair who came to the agency with an agenda to target PBMs. The Democratic Commissioners' public statements make clear that the outcome in this case is already foreordained, regardless of what the proceedings before the ALJ reveal and irrespective of whether the ALJ's recommended decision concludes that Express Scripts, Caremark, and Optum did not violate the law.

⁹⁴ Withrow v. Larkin, 421 U.S. 35, 46 (1975).

⁹⁵ Williams, 579 U.S. at 8.

⁹⁶ Jarkesy, 144 S. Ct. at 2141 (Gorsuch, J., concurring).

71. The current Commission's dramatic turn against PBMs vividly illustrates the prejudgment exhibited against Express Scripts, Caremark, and Optum in this case. Past Commissions have recognized the benefits of PBMs on a bipartisan basis and across administrations of both political parties. For example, past Commissions have observed that PBMs have the "ability to negotiate lower prices for prescription drugs," create incentives for pharmacies to bid aggressively on prescription drug prices, and that PBM formulary and generic substitution practices "lowers prescription drug costs" and "lower prices for health care" for consumers. Indeed, after its 2012 "comprehensive investigation" of the Express Scripts, Inc. acquisition of Medco Health Solutions (both of which are Respondents in the Commission's administrative action), the Commission concluded that competition among PBMs "is intense, has driven down prices, and has resulted in declining PBM profit margins."

⁹⁷ Letter from Susan S. DeSanti, Joseph Farrell & Richard A. Feinstein, FTC to State Rep. Mark Formby, Miss. H.R., at 1 (Mar. 22, 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf.

⁹⁸ *Id.* at 4.

⁹⁹ Letter from Maureen K. Ohlhausen, Michael A. Salinger & Jeffrey Schmidt, FTC to Terry G. Kilgore, Member, Va. House of Delegates, at 4, 6 (Oct. 2, 2006), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.terry-g.kilgore-concerning-virginia-house-bill-no.945-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-both-health-benefit/v060018.pdf.

¹⁰⁰ FTC, Statement Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., at 2, FTC File No. 111-0210 (Apr. 2, 2012), https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express./120402expressscripts.pdf.

72. The current Commission has decided to cast those findings aside in single-minded pursuit of its anti-PBM agenda. For example, in September 2022 testimony before a Subcommittee of the Senate Judiciary Committee, Chair Khan prejudged PBMs for having "opaque operations" and an ostensible ability to "dictate the pricing and access to life-saving drugs for so many Americans." Separately, she has disparaged PBMs as "obscure players" and "these middlemen" who "determine who gets access to what medicines and at what price." She has publicly singled out "PBMs" as "powerful corporate middlemen" who supposedly "engage in tactics that hike the price of drugs, deprive patients of access to certain medicines," and "price gouge[]" customers. She has referred to rebating on drugs as a form of "kickback" to PBMs, 105 which supposedly ensure that the "medicines that are made available at the pharmacy are not the

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In July 2023, the Commission suddenly voted to withdraw numerous prior letters, studies, and reports concerning the PBM industry. Those letters and reports had been produced by the FTC on a bipartisan basis over the course of multiple decades across the administrations of both political parties. The decision to disavow these letters and reports was made only by Chair Khan and the two other Democratic Commissioners—Commissioners Slaughter and Bedoya. Chair Khan claimed that the withdrawal of the FTC's prior data-driven and scholarly work was necessary because "these previous FTC documents may not reflect the current reality of the marketplace with respect to PBMs." Lina M. Khan, Chair, FTC, *Statement Regarding the Policy Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports*, at 1, FTC File No. P230100 (July 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/StatementofChairLinaMKhanrePBMLetterWithdrawal.pdf.

Lina M. Khan, Chair, FTC, *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the FTC Before the United States Senate Committee on the Judiciary Subcomm. on Antitrust, Competition Policy and Consumer Rights, at 14 (Sept. 20, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P210100SenateAntitrustTestimony09202022.pdf.

¹⁰³ Senator Bernie Sanders, *LIVE with FTC Chair Lina Khan* at 9:26–9:34, YOUTUBE (Apr. 15, 2024), https://www.youtube.com/watch?v=-C99FUnGnJU.

¹⁰⁴ Lina M. Khan, Chair, FTC, *Remarks as Prepared for Delivery White House Roundtable on PBMs*, at 1 (Mar. 4, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.03.04-chair-khan-remarks-at-the-white-house-roundtable-on-pbms.pdf.

Lina M. Khan, Chair, FTC, Remarks at the American Medical Association National Advocacy Conference, at 4 (Feb. 14, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/remarks-chair-khan-ama-national-advocacy-conference.pdf.

most affordable medicines for Americans"¹⁰⁶—echoing precisely the allegation later made later in the Commission's instant Complaint against Express Scripts, Caremark, and Optum. Chair Khan has also claimed that PBMs "are sitting right in the middle and controlling the types of practices that independent pharmacies are facing, the medicines that consumers are or have not been able to access, so we are looking at magnitude of harm [and] who are the most significant players in the supply chain."¹⁰⁷ And Chair Khan has declared that these "practices violate the fundamental bargain at the center of the American prescription drug system."¹⁰⁸

73. The Commission's Complaint echoes or repeats nearly verbatim many of Chair Khan's favored jabs against PBMs. For example, it alleges that PBMs "are central actors in pharmaceutical transactions, influencing drug pricing, rebates, and sales" and that PBMs "have created an opaque drug pricing and reimbursement system." It claims that the "PBM Respondents have a significant role in controlling consumers' affordable access to prescription medications." And it alleges that "[b]ecause of Respondents' conduct, many diabetics have been denied access to more affordable lower list price insulin products." Chair Khan has explicitly prejudged the facts and legal claims alleged in the Complaint.

¹⁰⁶ Senator Bernie Sanders, *LIVE with FTC Chair Lina Khan*, at 9:48–10:17, YOUTUBE (Apr. 15, 2024), https://www.youtube.com/watch?v=-C99FUnGnJU.

¹⁰⁷ Economic Liberties, *2023 Anti-Monopoly Summit*, at 1:22:40, YOUTUBE (May 4, 2023), https://www.youtube.com/watch?v=_MUdBWApI9k&t=3928s.

¹⁰⁸ Lina M. Khan, Chair, FTC, *Remarks Regarding Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, at 2, Commission File No. P221201 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Remarks-Chair-Lina-Khan-Regarding-Policy-Statement-Rebates-Fees.pdf.

¹⁰⁹ Complaint at 5 (Background).

¹¹⁰ *Id.* ¶ 7; see also ¶ 4.

¹¹¹ *Id.* at ¶ 263; see also ¶ 4.

 $^{^{112}}$ *Id.* at ¶ 218.

74. The two other Democratic Commissioners have also demonstrated that they, too, have already prejudged the issues central to the Commission's administrative action. Commissioner Slaughter has publicly declared that "[f]airness in drug pricing is undermined" by PBM rebates, concluding that "[t]his is not the way competition is supposed to work" and branding PBMs by association with "illegal anticompetitive practices." She has also attributed increases in "patients' out-of-pocket costs" to "mushroom[ing]" "PBM rebates and fees." And she has accused PBMs of creating "disturbing[]," "unacceptable," and "rotten" market "distortions." 115

75. Commissioner Bedoya has concluded that it is "pretty clear" that rebates improperly "drive up the list price" for consumers, while declaring that rebates' effects can be "horrific" and "frankly, keep [him] up at night." Commissioner Bedoya has suggested that "[w]e all know" that PBM pricing is "not what fair markets look like." He has also disparaged

113 Rebecca Kelly Slaughter, Acting Chair, FTC, Statement Regarding the Federal Trade Commission's Report to Congress on Rebate Walls, at 1 (May 28, 2021), https://www.ftc.gov/system/files/documents/public_statements/1590532/statement_of_acting_chairwoman slaughter regarding the ftc rebate wall report to congress.pdf.

Rebecca Kelly Slaughter, Comm'r, FTC, Statement Regarding the Commission Statement on Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities, at 2 (July 20, 2023), https://www.ftc.gov/system/files/ftc gov/pdf/finalbksremarksonftcstatementagainstrelianceonpriorpbmadvocacy7202023.pdf.

¹¹⁵ Rebecca Kelly Slaughter, Comm'r, FTC, Statement Regarding the Use of Compulsory Process and Issuance of 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers, at 1 https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMSlaughterStatement. pdf.

¹¹⁶ Capital Forum, *Fireside Chat with FTC Commissioner Alvaro Bedoya*, at 4:30, YOUTUBE (Nov. 13, 2023), https://youtu.be/VkQCHB1IVrY; Capital Forum, Transcript of Interview with FTC Commissioner Alvaro Bedoya (June 15, 2023), https://thecapitolforum.com/resources/transcript-of-interview-with-ftc-commissioner-alvaro-bedoya.

¹¹⁷ Alvaro M. Bedoya, Comm'r FTC, *Returning to Fairness*, Prepared Remarks Before the Midwest Forum on Fair Markets, at 8 (Sept. 22, 2022), https://www.ftc.gov/system/files/ftc gov/pdf/returning to fairness prepared remarks commissioner alvaro bedoya.pdf.

PBMs as "the middlemen who control our access to insulin" and "make billions off it" by means of "placements on formularies." ¹¹⁸

76. These are among the key issues the Commission will confront in adjudicating its Complaint and are vigorously disputed by Plaintiffs. Yet as with Chair Khan, the Complaint echoes Commissioners Slaughter and Bedoya's prior statements. It alleges PBMs have created a "broken drug pricing system," which is "a pattern of anticompetitive and unfair conduct." It claims that PBMs' supposed "high rebates and fees" result in "higher out-of-pocket costs," and this "mode of competition [] is detrimental to patients."

77. The Commissioners' attacks on PBMs have often come at one-sided events hosted and funded by notoriously anti-PBM groups. For example, the Commissioners have spoken numerous times before a trade association and lobbying group that is openly hostile to PBMs. 123 Khan even headlined the group's 2022 convention, where executives described PBMs as "bloodsuckers," wore shirts depicting PBMs as vampires, and distributed "F*** PBM" pins. 124

¹¹⁸ Alvaro M. Bedoya, Comm'r, FTC, Statement Regarding Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, at 1, 3 (June 16, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P214501 BedoyaStatementRebatePolicy.pdf.

¹¹⁹ Complaint ¶ 8.

 $^{^{120}}$ *Id.* ¶ 214.

¹²¹ *Id.* ¶ 259.

 $^{^{122}}$ *Id.* ¶ 193.

¹²³ See, e.g., Celine Castronuovo, FTC Intends to 'Not Rush' Probe into Pharmacy Benefit Mangers, Bloomberg Law (Apr. 27, 2023), https://news.bloomberglaw.com/health-law-and-business/ftc-intends-to-not-rush-probe-into-pharmacy-benefit-managers.

¹²⁴ Cami Mondeaux, FTC Chairwoman Lina Khan Faces Ethics Complaint over Alleged Bias against Pharmacy Benefit Managers, Washington Examiner (Sept. 7, 2023), https://www.washingtonexaminer.com/news/2449295/ftc-chairwoman-lina-khan-faces-ethics-complaint-over-alleged-bias-against-pharmacy-benefit-managers/; CVS Health, Independent Pharmacies: Myths versus Reality, at 9 https://www.cvshealth.com/content/dam/enterprise/cvs-enterprise/pdfs/2024/drug-costs/2024-08-10-FTC-White-Paper-on-Independent-Pharmacies.pdf.

78. Chair Khan's Commission has also made similar statements about insulin specifically. In June 2022, the Commission issued a policy statement asserting that rebates from PBMs are a reason insulin prices increased in the past. The Commissioners also issued a press release demonizing PBMs' "illegal rebate schemes" as "bribes." Without waiting for the study's results, the Commissioners took the unusual step of releasing an interim report, marred by a politicized process and lack of evidence, that in its very title accuses PBMs of "inflating drug costs." The Complaint essentially repeats those same conclusions as allegations in the instant administrative action, showing that the fix is in. The Commission will ultimately decide Plaintiffs have violated the law and will enter its own industry-altering remedies, regardless of the evidence or the ALJ's findings or credibility determinations. This is not, as the Constitution requires, a process without an appearance of bias.

79. Worse still, the only votes authorizing the action against Plaintiffs were cast by the Democratic Commissioners due to the recusal of both Republican Commissioners. The rationale for these recusal decisions was not made public, and Express Scripts, Caremark, and Optum have

¹²⁵ FTC, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

¹²⁶ FTC, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (June 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

¹²⁷ FTC, Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. On September 17, 2024, Express Scripts filed a lawsuit in the Eastern District of Missouri concerning the PBM report against the FTC and Chair Khan in her official capacity alleging claims for defamation and violations of due process, Article II of the Constitution, the FTC Act, and the Administrative Procedure Act. *See Express Scripts, Inc. v. FTC et al.*, No. 4:24-cv-01263-SRC (E.D. Mo. Sept. 17, 2024).

no meaningful opportunity to challenge them with the Commission. The partisan origin of this high-stakes enforcement action raises further due process problems with the Commission's action because it circumvented one of the key procedural protections that Congress included in the FTC's structure: that the Commissioners would convene a *bipartisan* group that would make enforcement decisions jointly.

- 80. The bias against Express Scripts, Caremark, and Optum as to both the law and facts that pervades the Commission's administrative process makes it fundamentally unfair. The Commission's public position is so firmly entrenched—given the prejudgment reflected in numerous speeches, statements, and other issuances—that it makes it "difficult, if not impossible" for the Commission to "reach a different conclusion" in this adjudication against Express Scripts, Caremark, and Optum. Chair Khan and her Democratic Commissioner colleagues came to the FTC with an agenda to reverse the FTC's multi-decade and bipartisan conclusion that PBMs promote competition in the prescription drug industry and to sue the PBMs. The Democratic Commissioners' minds are irrevocably closed to the possibility that PBMs' conduct is procompetitive and pro-consumer, not anticompetitive and anti-consumer. Judicial intervention is therefore warranted to enjoin this unfair proceeding that runs roughshod over the PBMs' due process rights and falls short of embodying the "appearance of justice," given that "justice must satisfy the appearance of justice."
- 81. For the above reasons, Plaintiffs cannot realistically or fairly be expected to receive a fair hearing on these or other challenges to the Commission's constitutionally deficient

 $^{^{128}}$ Cinderella Career & Finishing Schools, Inc. v. FTC, 425 F.2d 583, 590 (D.C. Cir. 1970).

¹²⁹ Antoniu v. SEC, 877 F.2d 721, 724 (8th Cir. 1989) (quoting In re Murchison, 349 U.S. 133, 136 (1955)).

proceedings in the administrative process itself. Having decided to initiate this improper proceeding, there is no reason to believe that the Commission would change its mind now and respect the U.S. Constitution. Moreover, the Commission, which has no special expertise in analyzing and interpreting the Constitution, has consistently rejected such arguments when raised in the past.¹³⁰

E. Express Scripts, Caremark, and Optum Will Suffer Irreparable Harm Unless the Administrative Proceeding is Enjoined.

- 82. Multiple serious defects in the structure of the Commission and in the administrative proceeding, combined with the Commission's prejudgment of the facts and bias against Express Scripts, Caremark, and Optum, as outlined above, render the administrative proceeding unconstitutional.
- 83. Unless the proceeding is enjoined, Express Scripts, Caremark, and Optum will suffer an immediate constitutional injury by being subjected to an illegitimate proceeding. The harm from such illegitimate proceedings cannot be undone. The Supreme Court has recognized that the injury of being subjected to an illegitimate proceeding is a "'here-and-now injury.'" 131
- 84. Plaintiffs also face the independent irreparable harm of being deprived of fundamental constitutional liberties. Article II and Article III confer and protect individual

¹³⁰ See, e.g., Order Denying Motion to Disqualify, *In re Intuit Inc.*, Docket No. 9408 (F.T.C. Oct. 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/d09408_2023-10-19_intuit_order_denying_motion_to_disqualify_unsigned.pdf; Statement of Chair Lina M. Khan Regarding the Petition for Recusal from Involvement in Intuit Inc., *In re Intuit Inc.*, Docket No. 9408 (F.T.C. Oct. 19, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/statement_of_chair_lina_m_khan_re_intuit_inc.pdf; Order Denying Respondent's Motion to Disqualify the Administrative Law Judge, *In re Axon Enterprise, Inc. & Safariland, LLC*, Docket No. 9389 (F.T.C. Sept. 3, 2020), https://www.ftc.gov/system/files/documents/cases/d09389_order_denying_motion_to_disqualify_alj.pdf.

¹³¹ Axon, 598 U.S. at 191.

constitutional rights, in addition to vindicating interests in the appropriate separation of powers. ¹³² The Due Process Clause likewise protects individual rights to a fair and impartial adjudicator. The deprivation of fundamental constitutional rights, even if temporary, is an injury. ¹³³ And because the Commission's ongoing proceeding violates these constitutional rights, Plaintiffs' rights will continue to be lost every day, and their injuries will continue to mount. And these injuries cannot be remedied by judicial review of a final FTC order.

- 85. Express Scripts, Caremark, and Optum cannot obtain a fair hearing and remedy for this constitutional defect within the confines of the Commission's proceeding. The Federal Rules of Civil Procedure and the Federal Rules of Evidence do not apply there, and the Commission decides all questions of law. Although Express Scripts, Caremark, and Optum can and will make objections to preserve their rights, those objections will be decided ultimately by the three Commissioners participating in the administrative matter—all of whom have already demonstrated bias against Express Scripts, Caremark, and Optum and have prejudged the disputed facts.
- 86. As previously explained, any appeal from an adverse ALJ decision against Plaintiffs would go directly to the full Commission that voted to investigate and file the Complaint and has already prejudged the outcome, giving Plaintiffs no real recourse and guaranteeing a predetermined outcome. The Commission can rewrite the ALJ's factual conclusions when reviewing the ALJ's non-binding recommendation, meaning that Express Scripts, Caremark, and Optum will be deprived of an opportunity for a neutral decision-maker to make factual findings.
- 87. Put otherwise, Express Scripts, Caremark, and Optum are being backed into a corner with no fair options. The Commission has effectively already won by bringing this

¹³² See, e.g., Bond v. United States, 564 U.S. 211, 222 (2011) (explaining that "structural principles secured by the separation of powers" also "protect the individual").

¹³³ See Elrod v. Burns, 427 U.S. 347, 373 (1976).

proceeding in its home court. It will certainly win the administrative action, no matter what the evidence shows, because even if the ALJ rules in Plaintiffs' favor, the Commission, having prejudged the facts and law, will decline to accept the recommendation. Meanwhile, review in the Court of Appeals of any Commission decision—after millions of dollars in attorney's fees and countless hours of employee time and distraction—will be under a highly deferential standard with respect to the Commission's factual findings. Only this action can prevent the harms to Plaintiffs stemming from the Commission's unconstitutional proceeding.

COUNT ONE

Violation of Article III of the U.S. Constitution

- 88. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein. Article III requires the judicial power of the United States to be vested in Article III courts, and prohibits administrative agencies from adjudicating claims understood as part of that power at the Founding.
- 89. The Commissions' in-house proceeding under Section 5 of the FTC Act seeks to adjudicate unfair methods of competition and unfair or deceptive practices claims that are analogous to claims at common law that traditionally would have been litigated between private parties—claims involving private rights that must be tried in an Article III court.
- 90. The "public rights" exception does not permit the FTC to adjudicate unfair methods of competition and unfair or deceptive practices claims outside of an Article III court.
- 91. The FTC's adjudication of private rights in an in-house FTC proceeding violates Article III of the Constitution.

COUNT TWO

<u>Violation of Article II of the U.S. Constitution Because the FTC Commissioners Are</u> <u>Unlawfully Insulated from Removal</u>

- 92. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.
- 93. Article II of the Constitution vests the executive Power entirely in the President, who must "take Care that the Laws be faithfully executed."
- 94. Restrictions on the President's ability to remove subordinate officials who exercise significant executive power unlawfully trammel on presidential supervision of the officials and insulate the officials from political accountability in violation of Article II.
- 95. The for-cause removal restrictions enjoyed by FTC Commissioners flout these principles. The FTC exercises significant executive power and its Commissioners direct and control the work of the agency, yet the politically-accountable President is restricted in the ability to exercise the President's removal power over FTC Commissioners.
- 96. Because they exercise executive authority but are not freely removable by the President, the FTC Commissioners' insulation under Section 41 of the FTC Act violates Article II, Section 3 of the U.S. Constitution.

COUNT THREE

<u>Violation of Article II of the U.S. Constitution Because the FTC's ALJ Is Unlawfully</u> <u>Insulated from Removal</u>

- 97. Plaintiffs incorporate and reallege each allegation contained above, as though fully set forth herein.
- 98. Article II of the Constitution vests "the executive Power" entirely in the President, art. II, § 1, cl. 1, and thus the President must have the ability to remove subordinate officers whom exercise part of the executive power on the President's behalf.

- 99. The Supreme Court has thus held that the general rule is that the President must have the ability to remove his subordinates without restrictions. Specifically, the Supreme Court has held that two layers of for-cause removal protection unconstitutionally strip the President of the ability to supervise subordinate officers.
- 100. The FTC's ALJ in the underlying administrative proceeding exercising significant executive power in the administrative proceeding and is unconstitutionally insulated from presidential control by multiple layers of for-cause removal protection.
- 101. Because of the multiple levels of removal protection enjoyed by the FTC's ALJ, the President cannot remove the ALJ even if the President determines the ALJ is not properly exercising his duties or is discharging them improperly. Moreover, the ALJ is insulated from political accountability as a result of his multiple levels of removal protection.
- 102. The FTC ALJ's multiple for-cause removal protections violate Article II, and thus the proceeding before the unconstitutionally appointed ALJ is unlawful and violates the PBMs' rights.

COUNT FOUR

Violation of the Fifth Amendment to the U.S. Constitution

- 103. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.
- 104. Under the FTC Act, the FTC, as prosecutor, initiates or reopens an administrative proceeding in its discretion, and as judge, decides the matter, including through factual findings and legal determinations.
- 105. In the administrative action against Express Scripts, Caremark, and Optum, the FTC will act as both a prosecutor and judge. This dual role violates the PBMs' right to due process because it cannot receive a fair and unbiased hearing.

106. The Commissioners, including Chair Khan and the other Democratic Commissioners, have made statements suggesting that they have already made a decision on the merits against the PBMs and their minds are irrevocably closed to a different outcome. The other two Commissioners are recused.

- 107. After the administrative hearing, an Article III court cannot, according to the FTC, meaningfully review the FTC's decision, as the order will be subject to a highly deferential standard of review.
- 108. The FTC's unfettered authority to act as prosecutor and judge violates Plaintiffs' Fifth Amendment Due Process rights, including because the Commission has already decided the outcome of this proceeding.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants as follows:

- A declaratory judgment that the FTC's administrative action against Express Scripts,
 Caremark, and Optum violates Article III of the U.S. Constitution;
- ii. A declaratory judgment that the FTC Commissioners are unconstitutionally insulated from removal in violation of Article II of the U.S. Constitution, and thus the proceeding is unlawful;
- iii. A declaratory judgment that the that the FTC's ALJ is unconstitutionally insulated from removal in violation of Article II of the U.S. Constitution, and thus the proceeding is unlawful;
- iv. A declaratory judgment that the FTC's proceeding violates the Due Process Clause of the Fifth Amendment;

- v. An order preliminarily and permanently enjoining the FTC's unlawful administrative proceeding against Express Scripts, Caremark, and Optum;
- vi. Grant Plaintiffs such additional or other relief as it deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

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